



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-508P]

Proposed Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2020

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice with request for comments.

SUMMARY: The Drug Enforcement Administration (DEA) proposes to establish the 2020 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act (CSA) and assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

DATES: Interested persons may file written comments on this notice in accordance with 21 CFR 1303.11(c) and 1315.11(d). Electronic comments must be submitted, and written comments must be postmarked, on or before [INSERT 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

Based on comments received in response to this notice, the Administrator may hold a public hearing on one or more issues raised. In the event the Administrator decides in his sole discretion to hold such a hearing, the Administrator will publish a notice of any such hearing in the *Federal Register*. After consideration of any comments or objections, or

after a hearing, if one is held, the Administrator will publish in the *Federal Register* a final order establishing the 2020 aggregate production quotas for schedule I and II controlled substances, and an assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

ADDRESSES: To ensure proper handling of comments, please reference “Docket No. DEA-508P” on all correspondence, including any attachments. The Drug Enforcement Administration encourages that all comments be submitted electronically through the Federal eRulemaking Portal which provides the ability to type short comments directly into the comment field on the Web page or attach a file for lengthier comments. Please go to <http://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon completion of your submission you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on *Regulations.gov*. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. Paper comments that duplicate electronic submissions are not necessary and are discouraged. Should you wish to mail a paper comment *in lieu* of an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DRW, 8701 Morrisette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152, Telephone: (202) 598-6812.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received in response to this docket are considered part of the public record. They will, unless reasonable cause is given, be made available by the Drug Enforcement Administration (DEA) for public inspection online at <http://www.regulations.gov>. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

The Freedom of Information Act (FOIA) applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made publicly available, you must include the phrase “PERSONAL IDENTIFYING INFORMATION” in the first paragraph of your comment. You must also place all the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase “CONFIDENTIAL BUSINESS INFORMATION” in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment.

Comments containing personal identifying information or confidential business information identified and located as directed above will generally be made available in redacted form. If a comment contains so much confidential business information or personal identifying information that it cannot be effectively redacted, all or part of that

comment may not be made publicly available. Comments posted to <http://www.regulations.gov> may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this document is available at <http://www.regulations.gov> for easy reference.

Legal Authority

Section 306 of the CSA (21 U.S.C. 826) requires the Attorney General to establish aggregate production quotas for each basic class of controlled substance listed in schedules I and II, and for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. The Attorney General has delegated this function to the Administrator of the DEA pursuant to 28 CFR 0.100.

Analysis for Proposed 2020 Aggregate Production Quotas and Assessment of Annual Needs

The proposed year 2020 aggregate production quotas and assessment of annual needs represent those quantities of schedule I and II controlled substances, and the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, to be manufactured in the United States in 2020 to provide for the estimated medical, scientific, research, and industrial needs of the United States, lawful export requirements, and the establishment and maintenance of reserve stocks. These quotas include imports of ephedrine, pseudoephedrine, and phenylpropanolamine, but do not include imports of controlled substances for use in industrial processes.

In determining the proposed 2020 aggregate production quotas and assessment of

annual needs, the Acting Administrator has taken into account the criteria of 21 U.S.C. 826(a) and 21 CFR 1303.11 (aggregate production quotas for controlled substances) and 21 CFR 1315.11 (assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine).

Recent Changes to the Law and Regulations Governing Quotas

It should be noted that, as a result of new laws and regulations, the factors that DEA considers in setting aggregate production quotas have changed. First, under DEA's regulations as amended effective August 15, 2018 (83 FR 32784), when setting an aggregate production quota for any basic class of controlled substance listed in schedule I or II, DEA must now consider (in addition to the previously existing regulatory factors): (i) "[t]he extent of any diversion of the controlled substance in the class," and (ii) "[r]elevant information obtained from the Department of Health and Human Services [HHS], including from the Food and Drug Administration [FDA], the Centers for Disease Control [CDC], and the Centers for Medicare and Medicaid Services [CMS], and relevant information obtained from the states."

As a result, DEA regulations now list the following factors that the Administrator must consider in determining the aggregate production quotas: (1) total net disposal of each class or chemical by all manufacturers and chemical importers during the current and two preceding years; (2) trends in the national rate of net disposal of the class or chemical; (3) total actual (or estimated) inventories of the class or chemical and of all substances manufactured from the class or chemical, and trends in inventory accumulation; (4) projected demand for each class or chemical as indicated by procurement and import quotas requested in accordance with 21 CFR 1303.12, 1315.32,

and 1315.34; (5) the extent of any diversion of the controlled substance in the class; (6) relevant information obtained from HHS, including from the FDA, CDC, and CMS, and relevant information obtained from the states; and (7) other factors affecting medical, scientific, research, and industrial needs of the United States and lawful export requirements, as the Acting Administrator finds relevant, including changes in the currently accepted medical use in treatment with the class or the substances which are manufactured from it, the economic and physical availability of raw materials for use in manufacturing and for inventory purposes, yield and stability problems, potential disruptions to production (including possible labor strikes), and recent unforeseen emergencies such as floods and fires. 21 CFR 1303.11(b). These quotas do not include imports of controlled substances for use in industrial processes.

In addition to the foregoing regulatory changes, on October 24, 2018, the President signed into law the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act), Pub. L. 115-271, 132 Stat. 3894. The SUPPORT Act, which became effective upon its enactment, changed the way DEA must establish quotas with respect to five controlled substances: fentanyl, oxycodone, hydrocodone, oxymorphone, and hydromorphone. These five substances are referred to in the statute as “covered controlled substances.” The new law specifically provides that in establishing any quota under 21 U.S.C. 826, DEA is required to “estimate the amount of diversion of the covered controlled substance that occurs in the United States” and “make appropriate quota reductions, as determined by the [Administrator],”¹

¹ All functions vested in the Attorney General by the CSA have been delegated to the Administrator of DEA. 28 CFR 0.100(b).

from the quota the [Administrator] would have otherwise established had such diversion not been considered.” 21 U.S.C. 826(i)(1).

The SUPPORT Act further states: “In estimating diversion under this paragraph, the [Administrator] shall consider information the [Administrator], in consultation with the Secretary of [HHS], determines reliable on rates of overdose deaths and abuse and overall public health impact related to the covered controlled substance in the United States; and (ii) may take into consideration whatever other sources of information the [Administrator] determines reliable.”² *Id.*

Information Considered by DEA in Evaluating the Factors

For the factors listed in 21 CFR 1303.11(b)(1) and (2), the DEA solicited information from the FDA. In May 2019, DEA received FDA estimates of legitimate medical need for calendar years 2019 and 2020, as required by the statutes of both agencies. *See* 21 U.S.C. 826 and 42 U.S.C. 242. For the factors listed in 21 CFR 1303.11(b)(3) and (4), DEA registered manufacturers of controlled substances in schedules I and II provided the information by submitting their individual data to several DEA database systems used for reporting inventory, distribution, manufacturing, and estimated quota requirements to meet sales forecasts for each class of controlled substance as required by regulations. *See* 21 CFR 1303.12, 1303.22, and part 1304.

Factor 1303.11(b)(5) requires DEA to consider the extent of diversion of controlled substances. The estimates of diversion as required by the SUPPORT Act are discussed

² DEA intends to propose amendments to the Agency’s regulations that will implement the amendments to the CSA made by the SUPPORT Act. Although these amendments to the regulations have not yet been issued, the statutory requirements stated above became effective upon enactment of the SUPPORT Act, and DEA is therefore obligated to adhere to them in issuing these proposed aggregate production quotas.

later in the document. Diversion is defined as all distribution, dispensing, or other use of controlled substances for other than a legitimate medical purpose. In order to consider the extent of diversion, Federal, state, and local law enforcement seizures and registrant reports of diversion of controlled substances from 2018 were extracted from several DEA supported databases. As a result of considering the extent of diversion, DEA notes that the quantity of FDA-approved drug products that correlate to controlled substances in 2018 represents less than one percent of the total quantity of controlled substances distributed to retail purchasers. The databases used include:

- Theft Loss Report database comprised of DEA registrant reported entries documenting diversion consisting of employee theft, break-ins, armed robberies, and material lost in transit;
- Statistical Management Analysis & Reporting Tools System (SMARTS) database comprised of laboratory drug submissions from seizure data and drug purchases made by DEA task force groups, tactical diversion squads, enforcement groups, and High Intensity Drug Trafficking Area (HIDTA) task force groups;
- System to Retrieve Information on Drug Evidence (STRIDE) database comprised of material seized by numerous law enforcement groups across the country including the Federal Bureau of Investigation (FBI), DEA field offices, U.S. Immigration and Customs Enforcement (ICE) offices, Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) offices, and metropolitan police departments.

The DEA was able to identify usable information contained in the databases noted

above. The data was categorized by basic drug class and the amount of active pharmaceutical ingredient (API) in the dosage form was delineated with an appropriate metric for use in proposing aggregate production quota values (i.e. weight).

DEA's internal Automated Reports and Consolidated Ordering System (ARCOS) database was considered as well, however it was determined to contain identical information to the Theft Loss Report database because both are registrant reported databases, and therefore it was excluded. Additionally, both the National Seizure System (NSS) and the National Forensic Laboratory Information System (NFLIS) databases were reviewed. The NSS and NFLIS data reports included total seized weight without reference to whether it is finished dosage forms, container weight, tablets or pill weight; provides no reference to specific API concentrations; and the databases do not distinguish between pharmaceutically and illicitly manufactured controlled substances.

Because of factor six in 21 CFR 1303.11(b), DEA formally solicited HHS, CDC, CMS, and the states in August 2018, requesting information including rates of overdose deaths and abuse and overall public health impact related to controlled substances. This information was also considered pursuant to the SUPPORT Act. Based on the level of response, DEA sent a second letter to the states in October 2018. DEA sent a second letter to the CDC in April 2019 and CDC responded in June 2019. DEA in consultation with HHS and CDC discussed the requirements under the SUPPORT Act in June 2019.

As a result of these solicitations, DEA received Medicaid sales data from CMS, and drug overdose and death data from the CDC and seven state attorneys general. The CMS data consisted of aggregated sales of controlled substances to Medicaid patients. This information could not be used in determining diversion and therefore was not used in

setting the aggregate production quotas. The CDC and HHS do not have diversion data by individual controlled substance, but did provide documents and links to data sets and scholarly articles containing overdose and death rates at the national level. DEA determined that the current data could not be used to estimate diversion for the purpose of setting the aggregate production quotas. One major drawback is that the data does not examine each controlled substance individually (i.e. as a basic class and the quantity ingested), but groups them together chemically, making it difficult to determine which basic class was involved and to what extent its aggregate production quotas should be lowered. For example, patients that overdose from hydrocodone, oxycodone, or hydromorphone are grouped together under opioid-related overdose. DEA is unable to determine the basic class that led to the overdose from this information. Additionally, DEA cannot determine from the data if the patient overdosed on an illicit opioid or an FDA-approved opioid product. For purposes of setting the aggregate production quotas for each basic class of controlled substance, DEA would benefit more from the drug overdose and mortality data if it precisely identified the controlled substance(s) believed to be the cause of overdose or death and if it included the quantity of the substance ingested. DEA and HHS are working together to determine if this data currently exists in any reliable databases.

Nine state attorneys general responded to the DEA's request for information. Seven provided, in general, prescription data (from prescription drug monitoring programs), overdose and death rate data, in addition to statements regarding the over prescription of opioid medications and its effect on public health. The other states were not able to or did not provide the requested data. DEA examined the information submitted and

determined that it is too generalized to use in estimating diversion because the controlled substances are grouped together chemically. Toxicity reports, moreover, show all the drugs in a patient's system when arriving at the hospital or emergency room, which makes it difficult to know how much and which drug is responsible for the visit and consequently adjust its individual aggregate production quota. Additionally, there is no way to determine if the substance was manufactured illicitly or was an FDA-approved drug product. The manufacturing of illicit substances is not considered when determining the aggregate production quotas because such illicit manufacturing cannot be tempered by adjusting the aggregate production quotas. The information provided is highly valuable to understanding the impact of substance use, misuse, and abuse on the public health, but in its current form is not usable for the aggregate production quota analysis. Other factors the Acting Administrator considered in calculating the aggregate production quotas, but not the assessment of annual needs, include product development requirements of both bulk and finished dosage form manufacturers, and other pertinent information. In determining the proposed 2020 assessment of annual needs, the DEA used the calculation methodology previously described in the 2010 and 2011 assessment of annual needs (74 FR 60294, Nov. 20, 2009, and 75 FR 79407, Dec. 20, 2010, respectively).

Estimates of Diversion Pursuant to the SUPPORT Act

To estimate diversion as is required by the SUPPORT Act, DEA aggregated the API of each covered controlled substance by metric weight where the data was available in the aforementioned databases. Based on the individual entries into the aforementioned databases, DEA calculated the estimated amount of diversion by multiplying the strength

of the API listed for each finished dosage form by the total amount of units reported to estimate the metric weight in kilograms of the controlled substance being diverted. The estimate of diversion for each of the covered controlled substances is reported below.

Diversion Estimates for 2018 (kg)	
Fentanyl	0.109
Hydrocodone	24.259
Hydromorphone	1.219
Oxycodone	57.051
Oxymorphone	1.157

In accordance with the SUPPORT Act, after estimating the amount of diversion for the foregoing five controlled substances, DEA made reductions to the individual aggregate production quotas for each covered controlled substance by the corresponding quantities listed in the table.

The SUPPORT Act mandates that DEA, in consultation with HHS, determine reliable rates of overdose deaths, abuse, and overall public health impact as a factor of diversion to make appropriate quota reductions for each of the covered controlled substances. During the June 2019 consult with HHS, it was determined that the current available data regarding rates of overdose deaths and public health impact does not reflect each controlled substance individually (i.e. as a basic class and the quantity ingested), but groups them together functionally (opioid or psychostimulant), without regard to illicit or licit manufacturing. Without specificity to basic class and whether the substance was lawfully manufactured, DEA is unable to determine the basic class that led to the overdose from this information. Additionally, DEA cannot determine from the data if the patient overdosed on an illicit opioid or an FDA approved opioid product. As such, the number of overdose deaths resulting from fentanyl, oxycodone, hydrocodone,

hydromorphone, and oxymorphone diverted from legitimate sources is unknown.

As discussed above, DEA considers the extent of diversion of all controlled substances and estimates diversion of covered controlled substances, as is required by the recent amendments to the CSA and changes to DEA's own regulations. The information maintained in the various DEA databases discussed above assists the agency in identifying some forms of diversion of controlled substances. DEA is committed to improving its ability to account for other types of diversion.

The Acting Administrator, therefore, proposes to establish the 2020 aggregate production quotas for certain schedule I and II controlled substances and assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in grams of anhydrous acid or base, as follows:

Basic Class	Proposed 2020 Quotas
	(g)
Schedule I	
1-[1-(2-Thienyl)cyclohexyl]pyrrolidine	20
1-(1-Phenylcyclohexyl)pyrrolidine	15
1-(2-Phenylethyl)-4-phenyl-4-acetoxypiperidine	10
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	30
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	30
1-Benzylpiperazine	25
1-Methyl-4-phenyl-4-propionoxypiperidine	10
1-[1-(2-Thienyl)cyclohexyl]piperidine	15
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E)	30
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D)	30
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N)	30
2-(2,5-Dimethoxy-4-n-propylphenyl)ethanamine (2C-P)	30
2-(2,5-Dimethoxyphenyl)ethanamine (2C-H)	100
2-(4-Bromo-2,5-dimethoxyphenyl)-N-(2-	30

methoxybenzyl)ethanamine (25B-NBOMe; 2C-B-NBOMe; 25B; Cimbi-36)	
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C)	30
2-(4-Chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25C-NBOMe; 2C-C-NBOMe; 25C; Cimbi-82)	25
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I)	30
2-(4-Iodo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25I-NBOMe; 2C-I-NBOMe; 25I; Cimbi-5)	30
2,5-Dimethoxy-4-ethylamphetamine (DOET)	25
2,5-Dimethoxy-4-n-propylthiophenethylamine	25
2,5-Dimethoxyamphetamine (DMA)	25
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-2)	30
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-4)	30
3,4,5-Trimethoxyamphetamine	30
3,4-Methylenedioxyamphetamine (MDA)	55
3,4-Methylenedioxymethamphetamine (MDMA)	50
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	40
3,4-Methylenedioxy-N-methylcathinone (methylone)	40
3,4-Methylenedioxypropylvalerone (MDPV)	35
3-FMC; 3-Fluoro-N-methylcathinone	25
3-Methylfentanyl	30
3-Methylthiofentanyl	30
4-Bromo-2,5-dimethoxyamphetamine (DOB)	30
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	25
4CN-Cumyl-Butanica, 1-(4-Cyanobutyl)-N-(2-phenylpropan-2-yl)-1H-indazole-3-carboximide	25
4-Fluoroisobutyl fentanyl	30
4-FMC; Flephedrone	25
4-MEC; 4-Methyl-N-ethylcathinone	25
4-Methoxyamphetamine	150
4-Methyl-2,5-dimethoxyamphetamine (DOM)	25
4-Methylaminorex	25
4-Methyl-N-methylcathinone (mephedrone)	45
4-Methyl- α -pyrrolidinopropiophenone (4-MePPP)	25
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	50
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47,497 C8-homolog)	40
5F-CUMYL-PINACA	25
5F-EDMB-PINACA	25
5F-MDMB-PICA	25
5F-AB-PINACA; N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide	25

5F-CUMYL-P7AICA; (1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-pyrrolo[2,3-b]pyridine-3-carboximide)	25
5F-ADB; 5F-MDMB-PINACA (methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate)	30
5F-AMB (methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3-methylbutanoate)	30
5F-APINACA; 5F-AKB48 (<i>N</i> -(adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide)	30
5-Fluoro-PB-22; 5F-PB-22	20
5-Fluoro-UR144, XLR11 ([1-(5-fluoro-pentyl)-1H-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone	25
5-Methoxy-3,4-methylenedioxyamphetamine	25
5-Methoxy-N,N-diisopropyltryptamine	25
5-Methoxy-N,N-dimethyltryptamine	25
AB-CHMINACA	30
AB-FUBINACA	50
AB-PINACA	30
ADB-FUBINACA (<i>N</i> -(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide)	30
Acetorphine	25
Acetyl Fentanyl	100
Acetyl- <i>alpha</i> -methylfentanyl	30
Acetyldihydrocodeine	30
Acetylmethadol	2
Acryl Fentanyl	25
ADB-PINACA (<i>N</i> -(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide)	50
AH-7921	30
Allylprodine	2
Alphacetylmethadol	2
<i>alpha</i> -Ethyltryptamine	25
Alphameprodine	2
Alphamethadol	2
Alphaprodine	25
<i>alpha</i> -Methylfentanyl	30
<i>alpha</i> -Methylthiofentanyl	30
<i>alpha</i> -Methyltryptamine (AMT)	25
<i>alpha</i> -Pyrrolidinobutiophenone (α -PBP)	25
<i>alpha</i> -Pyrrolidinopentiophenone (α -PVP)	25
Aminorex	25
Anileridine	20
APINACA, AKB48 (<i>N</i> -(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide)	25
Benzethidine	25

Benzylmorphine	30
Betacetylmethadol	2
<i>beta</i> -Hydroxy-3-methylfentanyl	30
<i>beta</i> -Hydroxyfentanyl	30
<i>beta</i> -Hydroxythiofentanyl	30
Betameprodine	25
Betamethadol	4
Betaprodine	25
Bufotenine	15
Butylone	25
Butyryl fentanyl	30
Cathinone	40
Clonitazene	25
Codeine methylbromide	30
Codeine-N-oxide	192
Cyclopentyl Fentanyl	30
Cyclopropyl Fentanyl	20
Cyprenorphine	25
Desomorphine	25
Dextromoramide	25
Diapromide	20
Diethylthiambutene	20
Diethyltryptamine	25
Difenoxin	9,200
Dihydromorphine	753,500
Dimenoxadol	25
Dimepheptanol	25
Dimethylthiambutene	20
Dimethyltryptamine	50
Dioxyaphetyl butyrate	25
Dipipanone	5
Drotebanol	25
Ethylmethylthiambutene	25
Etorphine	30
Fenethylline	30
Fentanyl related substances	40
FUB-144	25
FUB-AKB48	25
Furanyl fentanyl	30
Furethidine	25
<i>gamma</i> -Hydroxybutyric acid	25,417,000
Heroin	45

Hydromorphenol	40
Hydroxypethidine	25
Ibogaine	30
Isobutyl Fentanyl	25
JWH-018 and AM678 (1-Pentyl-3-(1-naphthoyl)indole)	35
JWH-019 (1-Hexyl-3-(1-naphthoyl)indole)	45
JWH-073 (1-Butyl-3-(1-naphthoyl)indole)	45
JWH-081 (1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole)	30
JWH-122 (1-Pentyl-3-(4-methyl-1-naphthoyl)indole)	30
JWH-200 (1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole)	35
JWH-203 (1-Pentyl-3-(2-chlorophenylacetyl)indole)	30
JWH-250 (1-Pentyl-3-(2-methoxyphenylacetyl)indole)	30
JWH-398 (1-Pentyl-3-(4-chloro-1-naphthoyl)indole)	30
Ketobemidone	30
Levomoramide	25
Levophenacymorphan	25
Lysergic acid diethylamide (LSD)	40
MAB-CHMINACA; ADB-CHMINACA (<i>N</i> -(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1 <i>H</i> -indazole-3-carboxamide)	30
MDMB-CHMICA; MMB-CHMINACA(methyl 2-(1-(cyclohexylmethyl)-1 <i>H</i> -indole-3-carboxamido)-3,3-dimethylbutanoate)	30
MDMB-FUBINACA (methyl 2-(1-(4-fluorobenzyl)-1 <i>H</i> -indazole-3-carboxamido)-3,3-dimethylbutanoate)	30
MMB-CHMICA-(AMB-CHMICA); Methyl-2-(1-(cyclohexylmethyl)-1 <i>H</i> -indole-3-carboxamido)-3-methylbutanoate	25
Marihuana	3,200,000
Mecloqualone	30
Mescaline	25
Methaqualone	60
Methcathinone	25
Methoxyacetyl fentanyl	30
Methyldesorphine	5
Methyldihydromorphine	25
Morpheridine	25
Morphine methylbromide	5
Morphine methylsulfonate	5
Morphine-N-oxide	150
MT-45	30
Myrophine	25
NM2201; Naphthalen-1-yl 1-(5-fluoropentyl)-1 <i>H</i> -indole-3-carboxylate	25

<i>N,N</i> -Dimethylamphetamine	25
Naphyrone	25
<i>N</i> -Ethyl-1-phenylcyclohexylamine	5
<i>N</i> -Ethyl-3-piperidyl benzilate	10
<i>N</i> -Ethylamphetamine	24
<i>N</i> -Ethylpentylone, ephylone	30
<i>N</i> -Hydroxy-3,4-methylenedioxyamphetamine	24
<i>N</i> -Methyl-3-Piperidyl Benzilate	30
Nicocodeine	25
Nicomorphine	25
Noracymethadol	25
Norlevorphanol	55
Normethadone	25
Normorphine	40
Norpipanone	25
Ocfentanil	25
Ortho-fluorofentanyl, 2-fluorofentanyl	30
Para-chloroisobutyryl fentanyl	30
Para-fluorofentanyl	25
Para-fluorobutyryl fentanyl	25
Para-methoxybutyryl fentanyl	30
Parahexyl	5
PB-22; QUPIC	20
Pentedrone	25
Pentylone	25
Phenadoxone	25
Phenampromide	25
Phenomorphane	25
Phenoperidine	25
Pholcodine	5
Piritramide	25
Proheptazine	25
Properidine	25
Propiram	25
Psilocybin	30
Psilocyn	50
Racemoramide	25
SR-18 and RCS-8 (1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole)	45
SR-19 and RCS-4 (1-Pentyl-3-[(4-methoxy)-benzoyl]indole)	30
Tetrahydrocannabinols	384,460
Tetrahydrofuranfentanyl	15

Thebacon	25
Thiafentanil	25
Thiofentanyl	25
THJ-2201 ([1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone)	30
Tilidine	25
Trimeperidine	25
UR-144 (1-pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone	25
U-47700	30
Valeryl fentanyl	25
Schedule II	
1-Phenylcyclohexylamine	15
1-Piperidinocyclohexanecarbonitrile	25
4-Anilino-N-phenethyl-4-piperidine (ANPP)	813,005
Alfentanil	3,260
Alphaprodine	2
Amobarbital	20,100
Amphetamine (for conversion)	14,137,578
Amphetamine (for sale)	42,400,000
Bezitramide	25
Carfentanil	20
Cocaine	82,127
Codeine (for conversion)	3,225,000
Codeine (for sale)	30,731,558
Dextropropoxyphene	35
Dihydrocodeine	156,713
Dihydroetorphine	2
Diphenoxylate (for conversion)	14,100
Diphenoxylate (for sale)	770,800
Ecgonine	88,134
Ethylmorphine	30
Etorphine hydrochloride	32
Fentanyl	813,005
Glutethimide	25
Hydrocodone (for conversion)	1,250
Hydrocodone (for sale)	34,836,854
Hydromorphone	3,054,479
Isomethadone	30
Levo-alphacetylmethadol (LAAM)	5
Levomethorphan	30
Levorphanol	38,000
Lisdexamfetamine	21,000,000

Meperidine	1,463,873
Meperidine Intermediate-A	30
Meperidine Intermediate-B	30
Meperidine Intermediate-C	30
Metazocine	15
Methadone (for sale)	22,278,000
Methadone Intermediate	24,064,000
Methamphetamine	1,213,603
[678,878 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 505,231 grams for methamphetamine mostly for conversion to a schedule III product; and 29,494 grams for methamphetamine (for sale)]	
Methylphenidate	57,438,334
Metopon	25
Moramide-intermediate	25
Morphine (for conversion)	4,089,000
Morphine (for sale)	29,353,655
Nabilone	62,000
Noroxymorphone (for conversion)	19,169,340
Noroxymorphone (for sale)	376,000
Opium (powder)	250,000
Opium (tincture)	530,837
Oripavine	28,705,000
Oxycodone (for conversion)	914,010
Oxycodone (for sale)	72,593,983
Oxymorphone (for conversion)	24,525,540
Oxymorphone (for sale)	1,290,051
Pentobarbital	25,850,000
Phenazocine	25
Phencyclidine	35
Phenmetrazine	25
Phenylacetone	40
Piminodine	25
Racemethorphan	5
Racemorphan	5
Remifentanil	3,000
Secobarbital	172,100
Sufentanil	4,000
Tapentadol	13,447,541
Thebaine	70,829,235
List I Chemicals	
Ephedrine (for conversion)	25
Ephedrine (for sale)	4,136,000
Phenylpropanolamine (for conversion)	14,100,000

Phenylpropanolamine (for sale)	7,990,000
Pseudoephedrine (for conversion)	1,000
Pseudoephedrine (for sale)	174,246,000

The Acting Administrator further proposes that aggregate production quotas for all other schedule I and II controlled substances included in 21 CFR 1308.11 and 1308.12 remain at zero. In accordance with 21 CFR 1303.13 and 1315.13, upon consideration of the relevant factors, the Acting Administrator may adjust the 2020 aggregate production quotas and assessment of annual needs as needed.

Conclusion

After consideration of any comments or objections, or after a hearing, if one is held, the Acting Administrator will issue and publish in the *Federal Register* a final order establishing the 2020 aggregate production quota for controlled substances in schedules I and II and establishing an assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, 21 CFR 1303.11(c) and 1315.11(f).

Dated: September 6, 2019

Uttam Dhillon,
Acting Administrator.

Billing Code 4410-09-P

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